

October 13, 1995, now abandoned, which is in turn a continuation of application number 08/251,349, filed May 31, 1994, now abandoned. --.

## In the Claims

Please cancel claims 1-25.

Please add new claims 26-80 as follows:

- 26. A method for forcing cardiac output during hemodynamically compromising malfunction in a patient, comprising the steps of:
  - positioning a plurality of electrodes proximate portions of a patient's heart so that the electrodes may deliver electrical pulses which will be transmitted through the patient's heart;
  - (b) providing circuitry for detecting the presence of a hemodynamically compromising malfunction in the patient;
- (c) detecting the presence of hemodynamically compromising malfunction in the patient;
  - (d) delivering electrical current pulses through the patient's heart, via said electrodes after detecting hemodynamically compromising malfunction, said electrical current pulses having a voltage less than a normal defibrillation voltage level, to force contraction in the patient's muscles and to facilitate a minimum level of cardiac output until cessation of the hemodynamically compromising malfunction or until other medical intervention is provided; and
  - (e) delivering further medical intervention if the desired minimum level of cardiac output has not occurred, said medical intervention comprising delivering at lease one defibrillation pulse to the patient following a plarality of said electrical current pulses.

- 37. The method of claim 26, further comprising the steps of reassessing the presence of an hemodynamically compromising malfunction at predetermined intervals and terminating said delivery of electrical current pulses or defibrillation pulses if the hemodynamically compromising malfunction is no longer present.
- 28. The method of claim 26, in which each electrical current pulse has a voltage of between 10 and 350 volts.
- 29. The method of claim 26, further comprising the steps of monitoring cardiac output and adjusting said electrical current pulse with respect to amplitude to maintain a predetermined level of cardiac output, thereby conserving electrical energy.
- 30. The method of chaim 26, wherein a plurality of said electrical current pulses have rounded edges.
- 31. The method of claim 26, further comprising the step of forming a plurality of said electrical current pulses as a train of up to 50 narrow pulses.
- 32. The method of claim 26, wherein said the electrical current pulses are between 2 and 100 ms in width
- 33. The method of claim 26, wherein the step of delivering electrical current pulses comprises delivery of a plurality of pulses which are greater than about 250mA.
- 34. The method of claim 26, wherein said step of delivering electrical current pulses is performed immediately after detecting tachyarrhythmia.
- 35. The method of claim 26, wherein said defibrillation pulse is delivered to the patient internally.

- A method for producing minimal cardiac output on an emergency basis in a patient experiencing arrhythmia, comprising the steps of:
  - positioning a plurality of electrodes to enable delivery of electrical pulses which will be transmitted through portions of the patient's heart;
  - (b) \providing means for detecting the presence of arrhythmia in the patient;
  - (c) detecting the presence of arrhythmia in the patient;
  - (d) delivering a defibrillation pulse within the patient's body; and
  - delivering electrical current pulses through the patient's body, via said electrodes after said defibrillation pulse delivery and after detecting arrhythmia, said electrical current pulses having a voltage greater than that which would only pace the heart and less than that which would defibrillate the patient's heart, so as to force some contraction in the patient's heart, whereby a minimum level of cardiac output is maintained until cessation of the arrhythmia or until other medical intervention is provided.
- 37. The method of claim 36, in which the power supply provides electrical current pulses through the electrodes in a voltage range of greater than about 10 volts and less than about 350 volts.
- 38. The method of claim 36, in which the arrhythmia includes either tachycardia, asystole, or bradycardia.
- 39. The method of claim 36 in which the arrhythmia is of an asystole type relating to absence of cardiac contraction.
- 40. The method of claim 36, further comprising the step of electronically interfacing said means for detecting the presence of arrhythmia in the patient with said other medical intervention.
- 41. The method of claim 36, wherein the step of delivering electrical current pulses comprises delivery of a plurality of pulses which are greater than about 250mA.

- An at least partially implantable system, for internal use on a human body, for maintaining some cardiac output of a patient's heart during hemodynamically compromising malfunction using electrical forcing fields, comprising:
  - (a) power supply;
  - (b) \ arrhythmia detector connected to said power supply;
  - (c) pulse delivery circuitry connected to said power supply for delivering multiple electrical current pulses through portions of the patient's upper body;
  - (d) output control circuitry connected to said arrhythmia detector, said power supply, and said pulse delivery circuitry for controlling the delivery of multiple electrical current pulses to the patient's upper body after the detection of arrhythmia, said electrical current pulses having a voltage level less than the voltage necessary to defibrillate the patient, said output control circuitry providing pulses suitable for only producing contraction in the patient's body sufficient to maintain a level of cardiac output which is a fraction of the normal maximum cardiac output until cessation of the hemodynamically compromising malfunction or until other medical intervention is provided; and
  - (e) internal defibrillation means cooperating with said output control means and adapted for delivering at least one internal defibrillation pulse to the patient's body.
- 43. The system of claim 42, in which said electrical current pulses are delivered at a rate between about 60 and 200 beats per minute.
- 44. The system of claim 42, further comprising cardiac output sensing means.
- 45. The system of claim 42, in which the electrical current pulses are composed of several smaller pulses.
- 46. The system of claim 42, further comprising a blood pressure monitoring sensor connected to said arrhythmia detector.
- 47. The system of claim 42, in which the electrical current pulses are between 2 and 100 ms in width.

- The system of claim 42, in which said blood pressure monitoring means monitors cardiac output and further comprises means for adjusting said electrical current pulse amplitude by said output control circuitry output control circuitry to maintain an optimum therapy for maintaining cardiac output.
- 49. The system of claim 42, in which the electrical current pulses are between 2 and 50 ms in width.
- 50. The system of claim 42, in which said electrical current pulses are each a train of at least 10 narrow pulses.
- The system of claim 42, in which said arrhythmia detector comprises means for reassessing the presence of hemodynamically compromising malfunction at predetermined intervals and stopping said electrical current pulses with said output control circuitry if the hemodynamically compromising malfunction is no longer present.
- 52. The system of claim 42/in which said arrhythmia detector reassesses the presence of hemodynamically compromising malfunction and cardiac output at predetermined intervals and adjusts said electrical current pulses with said output control circuitry according to said reassessment.
- The system of claim 42, in which said power supply and said output control circuitry deliver said electrical current pulses at a level to maintain cardiac output for at least about 30 minutes.
- 54. The system of claim 42, wherein said output control circuitry delivers said electrical current pulses at a voltage between 10 and 350 volts.

- The system of claim 42, in which the power supply, the output control means, and the hemodynamically compromising malfunction detector operate to produce a cardiac output of between about 10% and about 90% of the normal maximum cardiac output for the patient.
- 56. The system of claim 42, in which the power supply, the output control means, and the hemodynamically compromising malfunction detector operate to produce a cardiac output of between about 20% and about 80% of the normal maximum cardiac output for the patient.
- 57. The system of claim 42, in which the power supply, the output control means, and the hemodynamically compromising malfunction detector operate to produce a cardiac output of greater than about 30% of the normal maximum cardiac output for the patient.
- 58. The system of claim 42, wherein the electrical current pulses are between 50 and 200 volts.
- 59. An implantable device for maintaining some cardiac output of a patient's heart during malfunction using electrical forcing fields, comprising:
  - (a) power supply for providing power to pulse delivery circuitry, hemodynamically compromising malfunction detector, and output control circuitry;
  - (b) hemodynamically compromising malfunction detector operatively connected to said power supply;
  - (c) first pulse delivery circuitry operatively connected to said power supply for delivering multiple electrical current pulses through portions of the patient's upper body, said multiple electrical pulses comprising cardiac therapy responsive to the particular patient's cardiac malfunction;
  - (d) output control circuitry operatively connected to said hemodynamically compromising malfunction detector, said power supply, and said first pulse delivery circuitry for controlling the delivery of multiple electrical current pulses to the human heart after the detection of malfunction; said electrical current pulses having an amplitude suitable for delivery through portions of the patient's upper body and for contributing to

the mechanisms that produce contractions in the patient's muscles which cause only a fraction of the normal maximum cardiac output but enough cardiac output to maintain cardiac viability until cessation of the malfunction or until other medical intervention is provided; and

- (e) second pulse delivery circuitry operably interfaced with at least said output control circuitry for delivering at least one defibrillation pulse to the patient's body when further medical intervention is required.
- 60. The device of claim 59 in which the amplitude of the electrical current pulses is greater than 20 volts and less than a cardiac defibrillating voltage.
- 61. The device of claim 5\( \) in which the voltage is less than about 200 volts.
- 62. The device of claim 59 in which the voltage is less than about 350 volts.
- 63. The device of claim 59 in which the electrical current pulses are composed of several smaller pulses.
- 64. The device of claim 59, in which said electrical current pulses comprise pulses which are greater than about 140 mA.
- 65. The device of claim 59, in which said electrical current pulses comprise pulses which are between 2 and 100 ms in width.
- 66. The device of claim 59 in which the electrical current pulses are composed of up to 50 smaller pulses
- 67. A method for providing hemodynamic output of a heart during a hemodynamically compromising malfunction, comprising the steps of:

- positioning a plurality of electrodes in a patient's body proximate the patient's heart so that the electrodes may deliver or receive electrical pulses transmitted through portions of the patient's upper body and heart;
- (b) providing circuitry for detecting the presence of hemodynamically compromising malfunction in the patient;
- (c) detecting the presence of hemodynamically compromising malfunction in the patient;
  - (d) delivering a first series of electrical current pulses for a first period of time via said electrodes after detecting the malfunction; said electrical current pulses having a voltage less than a normal defibrillation voltage level but enough to force hemodynamic activity by mechanical and electrical responses of the patient's body to facilitate contractions in the patient's body and to facilitate a minimum level of cardiac output;
  - (e) determining the output status of the heart;
  - (f) if the output status of the heart requires, then delivering at least one electrical defibrillation pulse having a voltage level sufficient to defibrillate the patient's heart; and
  - (g) determining the output status  $\delta f$  the heart.
- 68. The method of claim 67, in which the electrical current pulses are composed of up to 50 smaller pulses.
- 69. The method of claim 67, in which the electrical current pulses are composed of several smaller pulses.
- 70. The method of claim 67, in which said electrical current pulses comprise pulses which are between 2 and 100 ms in width
- 71. The method of claim 67, in which the electrical current pulses are timed to coincide with the natural pumping of the patient's atria.
- 72. The method of claim 67, in which the electrical current pulses are of a voltage between 10 and 350 volts.

A method for providing hemodynamic output of a heart during arrhythmia, comprising the steps of:

- (a) positioning a plurality of electrodes within portions of a patient's body proximate the patient's heart for delivery or receipt of electrical pulses transmitted through portions of the patient's upper body and heart;
- (b) providing means for detecting the presence of hemodynamically compromising malfunction in the patient;
- (c) detecting the presence of hemodynamically compromising malfunction or low cardiac output in the patient;
- (d) delivering a first series of electrical current pulses for a first period of time, through the patient's heart, via electrodes after detecting said arrhythmia, said first series of electrical current pulses comprising at least one electrical current pulse having a voltage level suitable for defibrillating the patient's heart; and
- (e) delivering a second series of electrical current pulses for a first period of time, through a portion of the patient's upper body and heart, via said electrodes after detecting arrhythmia; said second series of electrical current pulses comprising a plurality of pulses having a voltage level less than a normal defibrillation voltage level but enough to force hemodynamic activity by contraction of the patient's heart and to facilitate a minimum level of cardiac output.
- 74. The method of claim 73 in which the electrical current palses are composed of several smaller pulses..
- 75. The method of claim 73 in which the arrhythmia is of an asystole type relating to absence of cardiac contraction.
- 76. The method of claim 73, in which the pulse widths of said second series pulses are between about 1 ms and about 50 ms.

- 77. The method of claim 73, in which the pulse widths of said second series pulses are greater than about 2 ms and less than about 100 ms.
- 78. A method for conducting emergency electrical cardiac output in a human, comprising the steps of:
  - (a) providing means for detecting the presence of hemodynamically compromising malfunction in the patient;
- (b) detecting the presence of hemodynamically compromising malfunction in the patient;
  - delivering electrical current pulses through the patient's body to the patient's heart via electrodes, after detecting the malfunction, at a voltage level of less than a defibrillating voltage level, to force contraction in patient muscles and to facilitate a minimum level of cardiac output until cessation of the hemodynamically compromising malfunction or until other medical intervention is provided; and
  - (d) providing further medical intervention by delivering a series of defibrillation pulses through the patient's body said series comprising at least one electrical current pulse having a voltage level sufficient to defibrillate the patient's heart.
- 79. The method of claim 78 in which the electrical current pulses are delivered at a rate of less than about 200 pulses per minute.
- 80. The method of claim 78 further comprising a third series of cardiac current pulses to the heart to assist cardiac function.

## REMARKS

The present communication responds to the Office Action mailed August 2, 2001 for the above-identified application. The Examiner indicated that the Applicants did not include a specific reference in the first sentence of the specification to prior applications to which the claim priority. The Examiner also issued a restriction requirement regarding claims 1-25.